



PATENT  
Customer No. 22,852  
Attorney Docket No. 03495.0133-06000 (*note new reference number*)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

|                             |   |                             |
|-----------------------------|---|-----------------------------|
| In re Application of:       | ) |                             |
|                             | ) |                             |
| Marc ALIZON et al.          | ) | Group Art Unit: 1648        |
|                             | ) |                             |
| Application No. 09/041,975  | ) | Examiner: Jeffrey S. Parkin |
|                             | ) |                             |
| Filing Date: March 13, 1998 | ) | Confirmation No: 4167       |
|                             | ) |                             |
| For: VARIANT OF LAV VIRUSES | ) |                             |

**Mail Stop AF**  
Commissioner for Patents  
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Sir:

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

A Pre-Appeal Brief Conference is requested in this application in accordance with the USPTO Notice dated June 20, 2005.

Claims 23, 25, 44-46, and 48-56 are pending in this application and are currently rejected. Claims 1-22, 24, 26-43, and 47 are cancelled.

**I. THE CLAIMS DO NOT LACK WRITTEN DESCRIPTION SUPPORT**

Clear error is present in the rejection of claims 23, 25, 44-46, and 48-56 under 35 U.S.C. 112, for allegedly failing to comply with the written description requirement of under 35 U.S.C. § 112, first paragraph. Despite the numerous structural limitations Applicants have added, the Office asserts that the skilled artisan would not conclude that Applicants were in possession of the claimed viruses. *Id.* at 5.

The Office also appears to believe that actual reduction to practice is required for Applicant to claim the recited HIV-1 variants. For example, the Office states that “[t]he disclosure fails to identify isolation, characterization, and nucleotide sequence of other variant HIV-1 MAL isolates.” *Id.* at 5.

Applicants respectfully traverse. Actual reduction to practice is not necessary for a disclosure to provide adequate written description support. As noted by the Revised Interim Written Description Guidelines Training Materials (“Guidelines”) (<http://www.uspto.gov/web/offices/pac/writtendesc.pdf>), written description support can be found through a consideration of identifying characteristics including structural limitations. Also see *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956. The limitations of the claims are either explicit structural limitations or recite limitations that have a well-known correlation between structure and function. When considered together, these structural limitations clearly define the range of HIV-1 variants falling within the scope of the claims and convey to the skilled artisan that Applicants were in possession of the invention.

**A. PERCENTAGE IDENTITY**

The pending claims include the explicit structural limitation that the claimed variant viruses exhibit specific ranges of identity to viral proteins of HIV<sub>BRU</sub>. The Office has rejected these claims on the grounds that “it is not readily manifest” if nucleotide sequences with this degree of identity would hybridize. Office Action, p. 1. However, the Office has provided no evidence that the nucleic acids would fail to

hybridize. The recited identities are explicit structural limitations as they define the range of variants falling within the scope of the claims. When combined with the additional structural limitations in the claims, the skilled artisan could immediately envisage the claimed viruses, and would conclude that Applicant's were in possession of the invention.

**B. BINDING TO ANTIBODIES**

The Office asserts that "simply ascertaining antigen-antibody binding employing polyclonal antisera will not provide any meaningful structural information" Office Action, p. 8. According to the Office, MAL variants and non-MAL variants have epitopes in common that are recognized by AIDS patient sera. *Id.*

Applicants respectfully traverse. The claims all include the limitation that the claimed HIV-1 variant virus binds antibodies in AIDS patient sera. Moreover, the antibodies are limited to those that specifically recognize the LAV strain deposited at the CNCM under No. I-641. It is well known in the art that antibodies exhibit specificity for their substrates. As noted by the Office, the range of variants that are recognized by the antibodies would include viral proteins with common epitopes. Office Action, p. 8. See Specification, page 35, lines 23 to 34. As such, the skilled artisan could immediately envisage the range of variants that fall within the scope of the claims.

Moreover, because the antibodies are further limited to those that are specifically bind the LAV strain deposited at CNCM under No. I-641, the HIV-1

variants are not limited to those that bind antibodies from any sera, but are limited to those that bind to the antibodies in the specifically recited sera. When combined with the additional structural limitations present in the claims, the structural limitation of binding to specific antibodies provides adequate written support to further demonstrate Applicants' possession of the claimed HIV-1 variants.

**C. GENETIC STRUCTURE**

The Office asserts that "[l]imitations directed toward canonical genetic organization of LAV<sub>MAL</sub> are not further limiting because all HIVs display the same genetic organization: 5'-LTR-gag-pol-vif-vpr-tat-ref-vpu-enf-nef-LTR-3." Office Action p. 6.

Applicants respectfully assert that the genetic organization of the claimed HIV-1 variants is further limiting because it provides an explicit structural element that excludes other potential genetic organizations. When combined with the other structural limitations present in the claims, this limitation further defines the range of variants that fall within the scope of the claims.

**D. HYBRIDIZATION**

The Office asserts that "restriction fragments and oligonucleotide probes derived from the parental MAL isolate would still hybridize to shared conserved regions" under stringent conditions, and that "no meaningful deduction could be made pertaining to the actual isolate detected." Office Action, p. 9.

Applicants respectfully assert that hybridization does provide a structural limitation that would enable the skilled artisan so envisage the claimed HIV-1 variants, particularly in view of the other structural limitations in the claims. As noted by the Guidelines, hybridization under stringent conditions essentially reveals a representative species of DNAs as the skilled artisan would not expect substantial variation in the DNAs that hybridize. Guidelines, pp. 36-37. As such, hybridization constitutes an additional structural limitation that would convey to the skilled artisan that Applicants were in possession of the invention.

**E. DIRECT REPEATS**

The Office rejected the claims for inclusion of "direct sequence repeat" for alleged indefiniteness. Office Action, p. 1. While Applicants contend that the specification adequately defines this term, Applicants also wish to point out that this limitation provides an additional structural limitation. A pattern of direct repeats has been shown in the claimed viruses, including exact repeats and repeats with one or two point mutations. See Figure 6. These mutations are all specific to HIV-1<sub>MAL</sub> and are clearly not shown in the other strains. Thus, these repeats distinguish the claimed variants from all other HIV-1 strains. When combined with the numerous structural limitations in the claims, this explicit structural limitation further indicates that Applicants were in possession of the claimed variants.

**CONCLUSION**

Applicants request withdrawal of the written description rejection. The pending claims recite numerous structural limitations including: 1) specific identity to proteins of another virus; 2) binding to specifically identified antibodies; 3) defined genetic structure; 4) hybridization under stringent conditions; and 5) presence of direct repeats. Taken together, these explicit and implicit structural limitations demonstrate that Applicants were in possession of the invention.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: April 5, 2007

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